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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,784	04/08/2005	Christoph Methfessel	100717-660(KGB)	5735

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EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

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07/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,784	METHFESSEL ET AL.	
	Examiner	Art Unit	
	UNSU JUNG	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) *14 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Examiner for the current application has been changed from Leon Y. Lum to Unsu Jung in Art Unit 1641. Any inquiry concerning this application should be directed to Unsu Jung, whose contact information is provided in the conclusion section of this Office Action.

Reopening of Prosecution after Appeal

2. In view of the Appeal Brief filed on March 19, 2010, PROSECUTION IS HEREBY REOPENED. Applicant's arguments in the Brief regarding combination of Mazet and Barbier have been that is fully considered and found persuasive. New grounds of rejections have been set forth below for the claimed invention.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Mark L. Shibuya/

Supervisory Patent Examiner, Art Unit 1641.

Rejections Withdrawn

3. The following prior art rejections have been withdrawn in favor of the new grounds of rejections set forth in this Office action.

- Rejection of claims 11-12 and 15-17 under 35 U.S.C. 103(a) as being unpatentable over Mazet *et al.* (Eur. J. Biochem., 210, 249-256 (1992)) in view of Barbier *et al.* (US 2004/0126817); and
- Rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Mazet in view of Barbier, both cited above, and further in view of Xu *et al.* (US 5,874,668).

New Grounds of Rejections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 11-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the membrane being electrically tight with a chamber to form upper and lower spaces divided by the membrane and one of the electrodes being in the upper space and another being in the lower space. According to the specification, electrodes are separated by the membrane, one electrode being on a side of the membrane facing away from the membrane body and another being on a side facing the membrane body (p15 and Fig. 1). Division of the two spaces by an electrically tight membrane (i.e. electrically insulated) is essential for measuring the electrical signal on a membrane body produced from an electrically conducting access is produced from a side of the membrane facing away from the membrane body to an interior of the membrane body by a gap junction as currently recited in the claims.

b. Claims 11-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the

necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: structural relationship between the membrane and electrodes. According to the specification, electrodes are separated by the membrane, one electrode being on a side of the membrane facing away from the membrane body and another being on a side facing the membrane body (p15 and Fig. 1). Such configuration of the electrodes is necessary for measuring electrical signal on a membrane body, in which an electrically conducting access is produced from a side of the membrane facing away from the membrane body to an interior of the membrane body as currently recited in the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (U.S. Patent No. 5,874,668, Feb. 23, 1999) (hereinafter "Xu") evidenced by Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, Garland Publishing, Inc., New York, pp958-960) (hereinafter "Alberts").

Xu anticipates instant claims by teaching a measuring arrangement for measuring an electrical signal on a membrane body (see entire document, particularly column 9, lines 35-65 and Fig. 4D). The measuring arrangement includes an electrical

measuring instrument (column 9, lines 39-65), electrodes (52 in Fig. 4D), and two cells (a membrane and a membrane body) with a gap junction channel formed between the cells (column 9, lines 48-50). An electrically conducting access is produced from a side of the membrane facing away from the membrane body to an interior of the membrane body by the gap junction (Fig. 4D).

Although Xu is silent on specifically disclosing that the gap junctions comprise connexins, it is well known in the art that the gap junctions are constructed from transmembrane proteins that form structures called connexons and a connexon is composed of a ring of six identical protein subunits called connexins as taught by Alberts (see entire document, particularly p959, *Gap-Junction Connexons Are Composed of Six Subunits*, 1st and 2nd paragraphs). Given the teachings of Alberts, one of ordinary skill in the art would recognize that the gap junction channel of Xu would inherently include transmembrane proteins, connexons, which are composed of connexins, present in the membranes of the two cells. The gap junction of Xu inherently having connexins is further supported by applicant's acknowledgement in the appeal Brief filed on March 19, 2010 (p11).

With respect to claim 12, Xu teaches that the cell, which includes a lipid bilayer membrane is placed on a support (Fig. 4D).

With respect to claim 13, Xu teaches cell membrane covering a micropipette (capillary, column 9, lines 48-50).

With respect to claim 15, Xu teaches a measuring arrangement as set forth above. Further, Xu teaches a method of measuring an electrical signal on a membrane body (column 9, lines 35-65).

With respect to claim 16, Xu teaches that the electrical signal being measured is electric current flowing through the membrane (column 9, lines 46-54).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (U.S. Patent No. 5,874,668, Feb. 23, 1999) (hereinafter "Xu") evidenced by Alberts (Molecular Biology of the Cell, 3rd edition, 1994, Garland Publishing, Inc., New York, pp958-960) in view of Barbier *et al.* (WO 02/063298 A2, published Aug. 15, 2002 and filed Jan. 31, 2002) ("Barbier") and Griffith (U.S. PG Pub. No. US 2003/0105165 A1, published June 5, 2003 and filed Oct. 31, 2001).

Xu evidenced by Alberts teaches a measuring arrangement and a method for measuring an electrical signal on a biological membrane body as set forth above. However, Xu evidenced by Alberts fails to teach a method of identifying an active agent affecting a property of a receptor/ion channel, which includes steps of brining the membrane body into contact with a test substance and determining whether the electrical signal has been affected by the presence of the test substance.

Barbier teaches a gap junction coupling assay for screening a large compound libraries to identify compounds, which modulate junctional transmission (see entire document, particularly p4, lines 13-15). Barbier teaches an assay in which an activation

of a receptor is induced by an agonist to produce a second messenger response in sender cells (such as an elevation of cAMP, p16, lines 7-23). The second messenger signal is detected in receiver cells, which is only possible in the presence of functional gap junction (p16, lines 7-23).

Griffith teaches that cAMP enhances the molecular permeability and electrical conductance of gap junctions (see entire document, particularly p8, paragraph [0085]).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to identify compounds affecting the function of gap junctions as taught by Barbier (which includes steps of brining a cell/membrane body into contact with an agonist/test substance and determining whether the electrical signal has been affected by the presence of the agonist/test substance) using the measuring arrangement of Xu as evidenced by Alberts in order to identify compounds modulating functional activities of gap junction. The advantage of identifying compounds modulating functional activities of gap junction provides the motivation to combine teachings of Xu evidenced by Alberts and Barbier. One of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in combining teaches of Xu evidenced by Alberts and Barbier since Griffith teaches that cAMP enhances the molecular permeability and electrical conductance of gap junctions and the measuring arrangement of Xu can be used for identifying physiologically and pharmaceutically important biomolecules and drug screening (column 3, lines 9-16).

Response to Arguments

12. Applicant's arguments with respect to claims 11-13 and 15-17 have been considered but are moot in view of the new ground(s) of rejection.

Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung
Primary Examiner
Art Unit 1641